GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1528
ANSWERED ON:03.08.2005
SALE OF ILLEGAL STENTS
Rao Shri Kavuru Samba Siva;Singh Baba Shri K.C.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the quantity of Drug Eluting Stents(DES) being imported in the country every year ;

(b) the name of the countries from where the stents are being imported ;

(c) whether the Government is aware that different brands of stents manufactured abroad are freely available in the country without any approval or licence from the Drug Controller of India ;

(d) if so, the details thereof with names of the companies selling the illegal stents; and

(e) the action taken by the Government against such companies and medical professional using such stents?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) As per the information made available by Directorate General of Foreign Trade, Ministry of Commerce & Industry, the item `Drug Eluting Stents (DES)` is not separately classified under ITC (HS) classification. Therefore, the data in respect of import of this item is not maintained.

(c) Internationally DES are classified as medical devices not as drugs. However, under the Drugs & Cosmetics Act, 1940 to regulate any medical device, it is to be notified as a `drug` under Section 3 b
(iv) of the Drugs and Cosmetics Act. Since DES has not been notified as a drug under D&C Act, therefore, the office of Drugs Controller (India) is not issuing approval or licences for manufacture, sale and distribution of the same.

(d) & (e) Does not arise.